



### **JURISDICTION AND VENUE**

1. Bio-Synthesis admits that the action brought by Plaintiffs purports to be an action arising under the patent laws of the United States. Bio-Synthesis admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1338(a). Except as expressly admitted herein, Bio-Synthesis denies the remaining allegations of paragraph 1.

2. Bio-Synthesis admits, without admitting to the validity of Plaintiffs' infringement claims, that it is subject to personal jurisdiction in this judicial district and division. Except as expressly admitted herein, Bio-Synthesis denies the remaining allegations of paragraph 2 to the extent they pertain to Bio-Synthesis. To the extent these allegations pertain to another Defendant, Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations and, on that basis, denies these allegations.

3. Bio-Synthesis admits, without admitting to the validity of Plaintiffs' infringement claims, that venue may be proper as to Bio-Synthesis in this judicial district pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) although not in this division. Except as expressly admitted herein, Bio-Synthesis denies the remaining allegations of paragraph 3 to the extent they pertain to Bio-Synthesis. To the extent these allegations pertain to another Defendant, Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations and, on that basis, denies these allegations.

### **PARTIES**

4. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 4 and, on that basis, denies said allegations.

5. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 5 and, on that basis, denies said allegations.

6. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 6 and, on that basis, denies said allegations.

7. Bio-Synthesis admits that the face of U.S. Patent No. 5,538,848 ("the '848 patent") shows it is entitled "Method for Detecting Nucleic Acid Amplification Using Self-Quenching Fluorescence Probe." Bio-Synthesis is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 7 and, on that basis, denies said allegations.

8. Bio-Synthesis admits that the face of U.S. Patent No. 5,723,591 ("the '591 patent") shows it is entitled "Self-Quenching Fluorescence Probe." Bio-Synthesis is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 8 and, on that basis, denies said allegations.

9. Bio-Synthesis admits that the face of U.S. Patent No. 5,876,930 ("the '930 patent") shows it is entitled "Hybridization Assay Using Self-Quenching Fluorescence Probe." Bio-Synthesis is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 9 and, on that basis, denies said allegations.

10. Bio-Synthesis admits that the face of U.S. Patent No. 6,030,787 ("the '787 patent") shows it is entitled "Hybridization Assay Using Self-Quenching Fluorescence Probe." Bio-Synthesis is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 10 and, on that basis, denies said allegations.

11. Bio-Synthesis admits that the face of U.S. Patent No. 6,258,569 ("the '569 patent") shows it is entitled "Hybridization Assay Using Self-Quenching Fluorescence Probe." Bio-Synthesis is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 11 and, on that basis, denies said allegations.

12. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 12 and, on that basis, denies said allegations.

13. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 13 and, on that basis, denies said allegations.

14. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 14 and, on that basis, denies said allegations.

15. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 12 and, on that basis, denies said allegations.

16. Bio-Synthesis admits the allegations in paragraph 16 of the FAC.

17. Bio-Synthesis admits that a small portion of its business is the manufacture, offer and sale of modified oligonucleotides. Bio-Synthesis denies that it dictates the applications for which its customers use its product. To the extent not explicitly admitted herein, the allegations of paragraph 17 are denied.

18. Bio-Synthesis denies all of the allegations of paragraph 18.

19. Bio-Synthesis denies all of the allegations of paragraph 19.

20. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 20 and, on that basis, denies said allegations.

21. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 21 and, on that basis, denies said allegations.

22. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 22 and, on that basis, denies said allegations.

23. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 23 and, on that basis, denies said allegations.

24. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 24 and, on that basis, denies said allegations.

25. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 25 and, on that basis, denies said allegations.

26. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 26 and, on that basis, denies said allegations.

27. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 27 and, on that basis, denies said allegations.

#### **FIRST CLAIM FOR RELIEF**

#### **INFRINGEMENT OF UNITED STATES PATENT NO. 5,538,848**

28. In response to paragraph 28 of the FAC, Bio-Synthesis realleges and incorporates by reference the answers stated in paragraphs 1-27 above.

29. Bio-Synthesis admits that the face of the 848 patent indicates it issued on July 23, 1996, and that Plaintiffs attached what purports to be a true and correct copy of this patent as Exhibit A to the FAC. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 29 and, on that basis, denies said allegations.

30. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 30 and, on that basis, denies said allegations.

31. Bio-Synthesis denies each and every allegation of paragraph 31.

32. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 32 and, on that basis, denies said allegations.

33. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 33 and, on that basis, denies said allegations.

34. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 34 and, on that basis, denies said allegations.

35. Bio-Synthesis denies the allegations contained in paragraph 35 to the extent they pertain to Bio-Synthesis. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 35 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

36. Bio-Synthesis denies the allegations contained in paragraph 36 to the extent they pertain to Bio-Synthesis. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 36 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

## **SECOND CLAIM FOR RELIEF**

### **INFRINGEMENT OF UNITED STATES PATENT NO. 5,723,591**

37. In response to paragraph 37 of the FAC, Bio-Synthesis realleges and incorporates by reference the answers stated in paragraphs 1-36 above.

38. Bio-Synthesis admits that the face of the '591 patent indicates it issued on March 3, 1998, and that Plaintiffs attached what purports to be a true and correct copy of this patent as Exhibit B to the FAC. Bio-Synthesis is without knowledge or information sufficient to form a

belief as to the remainder of the allegations contained in paragraph 38 and, on that basis, denies said allegations.

39. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 39 and, on that basis, denies said allegations.

40. Bio-Synthesis denies each and every allegation of paragraph 40.

41. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 41 and, on that basis, denies said allegations.

42. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 42 and, on that basis, denies said allegations.

43. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 43 and, on that basis, denies said allegations.

44. Bio-Synthesis denies the allegations contained in paragraph 44 to the extent they pertain to Bio-Synthesis. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 44 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

45. Bio-Synthesis denies the allegations contained in paragraph 45 to the extent they pertain to Bio-Synthesis. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 45 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

### **THIRD CLAIM FOR RELIEF**

#### **INFRINGEMENT OF UNITED STATES PATENT NO. 5,876,930**

46. In response to paragraph 46 of the FAC, Bio-Synthesis realleges and incorporates by reference the answers stated in paragraphs 1-45 above.

47. Bio-Synthesis admits that the face of the '930 patent indicates it issued on March 2, 1999, and that Plaintiffs attached what purports to be a true and correct copy of this patent as Exhibit C to the FAC. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 47 and, on that basis, denies said allegations.

48. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 48 and, on that basis, denies said allegations.

49. Bio-Synthesis denies each and every allegation of paragraph 49.

50. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 50 and, on that basis, denies said allegations.

51. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 51 and, on that basis, denies said allegations.

52. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 52 and, on that basis, denies said allegations.

53. Bio-Synthesis denies the allegations contained in paragraph 53 to the extent they pertain to Bio-Synthesis. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 53 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

54. Bio-Synthesis denies the allegations contained in paragraph 54 to the extent they pertain to Bio-Synthesis. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 54 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

**FOURTH CLAIM FOR RELIEF**

**INFRINGEMENT OF UNITED STATES PATENT NO. 6,030,787**

55. In response to paragraph 55 of the FAC, Bio-Synthesis realleges and incorporates by reference the answers stated in paragraphs 1-54 above.

56. Bio-Synthesis admits that the face of the '787 patent indicates it issued on February 29, 2000, and that Plaintiffs attached what purports to be a true and correct copy of this patent as Exhibit D to the FAC. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 56 and, on that basis, denies said allegations.

57. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 57 and, on that basis, denies said allegations

58. Bio-Synthesis denies each and every allegation of paragraph 58.

59. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 59 and, on that basis, denies said allegations.

60. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 60 and, on that basis, denies said allegations.

61. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 61 and, on that basis, denies said allegations.

62. Bio-Synthesis denies the allegations contained in paragraph 62 to the extent they pertain to Bio-Synthesis. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 62 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

63. Bio-Synthesis denies the allegations contained in paragraph 63 to the extent they pertain to Bio-Synthesis. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 63 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

**FIFTH CLAIM FOR RELIEF**

**INFRINGEMENT OF UNITED STATES PATENT NO. 6,258,569**

64. In response to paragraph 64 of the FAC, Bio-Synthesis realleges and incorporates by reference the answers stated in paragraphs 1-63 above.

65. Bio-Synthesis admits that the face of the '569 patent indicates it issued on July 10, 2001, and that Plaintiffs attached what purports to be a true and correct copy of this patent as Exhibit E to the FAC. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 65 and, on that basis, denies said allegations.

66. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 66 and, on that basis, denies said allegations

67. Bio-Synthesis denies each and every allegation of paragraph 67.

68. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 68 and, on that basis, denies said allegations.

69. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 69 and, on that basis, denies said allegations.

70. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 70 and, on that basis, denies said allegations.

71. Bio-Synthesis denies the allegations contained in paragraph 71 to the extent they pertain to Bio-Synthesis. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 71 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

72. Bio-Synthesis denies the allegations contained in paragraph 72 to the extent they pertain to Bio-Synthesis. Bio-Synthesis is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 72 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

#### **RESPONSE TO PLAINTIFFS' JURY DEMAND**

73. Bio-Synthesis states that Plaintiffs' jury demand does not require a response.

#### **RESPONSE TO PLAINTIFFS' PRAYER FOR RELIEF**

74. Bio-Synthesis denies that Plaintiffs are entitled to the relief sought, or any other relief.

#### **AFFIRMATIVE DEFENSES**

Further answering the FAC, Bio-Synthesis asserts the following defenses. Bio-Synthesis reserves the right to amend its Answer with additional defenses as further information is determined.

#### **FIRST DEFENSE**

##### **(Non-infringement of the Asserted Patents)**

75. Bio-Synthesis incorporates by reference paragraphs 1 through 74 of its Answer.

76. Bio-Synthesis has not infringed, contributed to the infringement of, or induced the infringement of any valid claim of the '848, '591, '930, '787, or '569 patents, and is not liable for infringement thereof.

**SECOND DEFENSE**

**(Invalidity of the Asserted Patents)**

77. Bio-Synthesis incorporates by reference paragraphs 1 through 74 of its Answer.

78. Upon information and belief, one or more claims of each of the '848, '591, '930, '787, and '569 patents are invalid for failing to comply with the provisions of the Patent Laws of the United States, including without limitation 35 U.S.C. §§ 101, 102, 103 and/or 112, and Plaintiffs' claims for relief are therefore barred.

**THIRD DEFENSE**

**(Lack of Standing to Sue)**

79. Bio-Synthesis incorporates by reference paragraphs 1 through 74 of its Answer.

80. Upon information and belief, Plaintiffs lack standing to sue because neither holds sufficient rights to one or more of the '848, '591, '930, '787, and/or '569 patents.

**FOURTH DEFENSE**

**(Prosecution History Estoppel)**

81. Bio-Synthesis incorporates by reference paragraphs 1 through 74 of its Answer.

82. Upon information and belief, to the extent that Plaintiffs attempt to assert infringement under the doctrine of equivalents, Bio-Synthesis believes that arguments and amendments contained in the prosecution history of the '848, '591, '930, '787, and/or '569 patents will estop or bar any claims for alleged infringement.

**FIFTH DEFENSE**

**(Unclean Hands)**

83. Bio-Synthesis incorporates by reference paragraphs 1 through 74 of its Answer.

84. Plaintiffs' claims for alleged infringement are barred or limited by the doctrine of unclean hands and other equitable doctrines.

**SIXTH DEFENSE**

**(Laches)**

85. Bio-Synthesis incorporates by reference paragraphs 1 through 74 of its Answer.

86. Plaintiffs' FAC is barred, in whole or in part, under the doctrine of laches.

**SEVENTH DEFENSE**

**(Unavailability of Relief)**

87. Bio-Synthesis incorporates by reference paragraphs I through 74 of its Answer.

88. Plaintiffs have failed to plead and meet the requirements of 35 U.S.C. § 271(b) and (c) and are not entitled to any alleged damages prior to providing any actual notice to Bio-Synthesis of the '848, '591, '930, '787, or '569 patents.

**EIGHTH DEFENSE**

**(Adequate Remedy at Law)**

89. Bio-Synthesis incorporates by reference paragraphs 1 through 74 of its Answer.

90. Plaintiffs' claims for injunctive relief are barred in light of the fact that Plaintiffs have an adequate remedy at law.

**NINTH DEFENSE**

**(Unavailability of Enhanced Damages)**

91. Bio-Synthesis incorporates by reference paragraphs 1 through 74 of its Answer.

92. Plaintiffs have failed to plead and meet the requirements of 35 U.S.C. §§ 284 and 285 for increased damages and attorneys' fees and are not entitled to any alleged damages prior to providing any actual notice to Bio-Synthesis of the '848, '591, '930, '787, or '569 patents.

**TENTH DEFENSE**

**(Failure to Mark)**

93 Bio-Synthesis incorporates by reference paragraphs 1 through 74 of its Answer.

94. Plaintiffs' claims for damages are barred or limited due to failure by Plaintiffs to allege compliance with, and failure to comply with, the requirements of 35 U.S.C. § 287.

**PRAYER FOR RELIEF**

WHEREFORE, Bio-Synthesis respectfully prays for the entry of judgment as follows:

A. Dismissing with prejudice any and all claims of Plaintiffs' FAC and ordering that Plaintiffs take nothing as a result of the FAC;

B. Judging the '848, '591, '930, '787, and '569 patents and their claims invalid;

C. Judging the '848, '591, '930, '787, and '569 patents and their claims unenforceable;

D. Judging that Bio-Synthesis has not and does not infringe, directly or indirectly, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '848, '591, '930, '787, and '569 patents;

E. That Plaintiffs be denied any remedies available under 35 U.S.C. § 284;

- F. That the Court denies Plaintiffs any injunctive relief;
- G. That the Court denies Plaintiffs any other relief;
- H. Finding that this is an exceptional case and awarding Bio-Synthesis its attorneys' fees as the prevailing party pursuant to 35 U.S.C. § 285;
- I. That the Court award Bio-Synthesis its costs of suit; and
- J. That the Court award such further relief as deemed just and proper.

Dated: January 14, 2010

Respectfully submitted,

**SHACKELFORD, MELTON & McKINLEY, LLP**

By: /s/ Nicole T. LeBoeuf

NICOLE T. LeBOEUF  
Texas Bar No. 00791091

3333 Lee Parkway, Tenth Floor  
Dallas, Texas 75219  
Telephone: (214)780-1499  
Facsimile: (214)780-1401

ATTORNEYS FOR BIO-SYNTHESIS, INC.

**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing document has been served on all counsel of record via the Court's Case Management/Electronic Case Filing system on January 14, 2010.

/s/ Nicole T. LeBoeuf  
Nicole T. LeBoeuf